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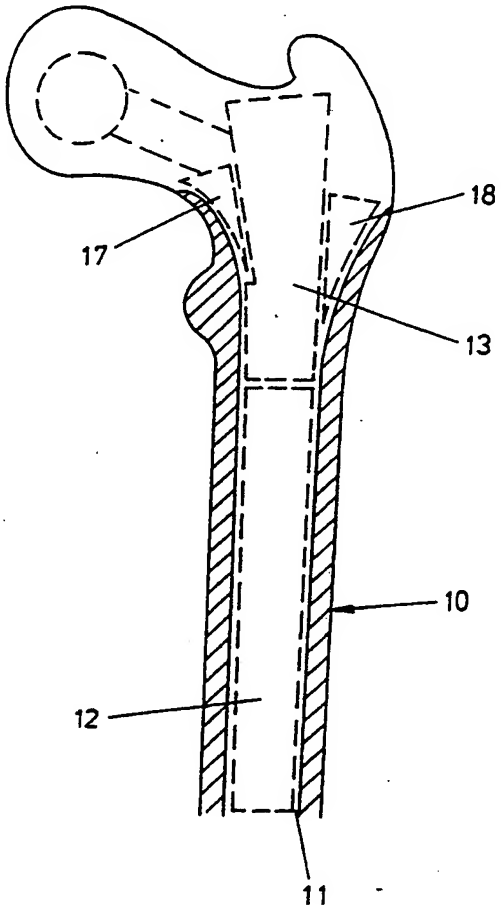
(54) Title: PROSTHETIC IMPLANT MANUFACTURE

(57) Abstract

A method of manufacture of a prosthetic device e.g. a hip joint prosthesis to be implanted in a particular bone cavity (11) comprises: preparing an image of the bone cavity, usually an x-ray image: providing a template which defines the required shape of an implant. In one embodiment one of a supply of template sheets having reference lines thereon can be lined-up with corresponding references on the image, and the required implant outline is marked on the sheet by any suitable manual marking means. In an alternative a template is selected from a range of templates of a general shape appropriate to the implant to be fitted in the bone cavity (11), and is compared with the image in order to determine whether it constitutes a suitable match. Then, the required shape of implant is manufactured, or selected from a preformed range of already manufactured implants corresponding with the range of templates.



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PROSTHETIC IMPLANT MANUFACTURE

This invention relates to a method of manufacture of a prosthetic implant of a form to suit the particular requirements of a patient.

The invention has been developed primarily in connection with the manufacture of hip implants for human use, but it should be understood that the invention has general application to the manufacture of prosthetic implants for human or animal use and including, inter alia, knee implants.

Conventionally, hip implants are made and supplied in either one of two ways. In a first technique, which is a pre-operative technique, a range of standard forms of implants e.g. different shapes and/or sizes, are manufactured and made available to surgeons, and it is then necessary to carry out necessary surgery to form a cavity of a suitable form to receive the selected form of implant. Thus, the femoral cavity will be prepared with approximately matching geometry to the implant, using a variety of different tools, including femoral rasps or broaches. One particularly advantageous recent improvement to a femoral rasp is disclosed in more detail in WO 90/03764.

In a second technique, pre-formed standard shapes/sizes of implants can be machined down to size to suit a pre-prepared femoral cavity in the manner disclosed in more detail in Stewal EP 0129531.

A disadvantage of the first technique is that it is limited in its ability to match ideally a limited range of pre-manufactured implants to the infinite range of anatomical geometry. A disadvantage of the second technique is that it is limited by the expense and inconvenience of providing the necessary plant and equipment close to the operating theatre as well as the evident risks associated with the short time available in which to carry out the manufacture, and also quality assurance problems. Thus, the implant has to be machined down to size following formation of a model from the

cavity formed in the patient.

The present invention therefore seeks to provide an improved method of manufacture of a prosthetic implant, the design of which can be derived accurately from patient parameters and without the necessity for pre-operative surgery to be carried out to set such parameters.

According to one aspect of the invention there is provided a method of manufacture of a prosthetic device of a form to be implanted in a particular bone cavity of a patient and which comprises:

preparing an image of the bone cavity:

providing a template which defines the required shape of an implant which is appropriate to the particular bone cavity:

visually comparing the image with the implant shape defined by the template to determine whether the implant shape constitutes a suitable match to the profile of the bone cavity, and if necessary providing an alternative implant shape for comparison with the image; and,

manufacturing an implant of a form corresponding with the implant shape defined by the template after an approved implant shape has been determined.

Preferably, the visual comparison takes place by arranging the image and the template one upon the other and conveniently the template is transparent, so that it can be positioned over the image. However, this is not essential to the invention, as evidently a transparent image sheet could be placed over a template (which may or may not be transparent) so that visual comparison can be made between the outline of the image and the outline of the preferred implant shape defined by the template.

The template may have the required shape of an implant applied thereon by the surgeon who will be carrying out the implantation of the prosthetic device, and this may be carried out by supplying template sheets having reference lines thereon, and which can be lined-up with corresponding references on the image, and the surgeon may then draw, or

use any other suitable means e.g. an electronic pen, to mark his own selection of the appropriate outline for the implant.

The surgeon may then compare his own selected outline closely with the image, and make any correction which he thinks advisable e.g. by erasing part of the previous outline, or by applying a fresh template with a new outline marked on it. The surgeon then passes the template to the manufacturer / supplier of implants, who then preferably converts the information into digital form, from which is derived outline elevational views of the implant, and preferably also a three dimensional illustration, all of which are then supplied to the surgeon for final approval before the required implant is taken from stock, or manufactured to order.

In the case of a hip prosthesis manufacture, the images of the bone cavity will usually be A / P (anterior / posterior) and lateral views, and the template will have reference lines corresponding with each view, so that the surgeon can mark out his preferred outline shape of the required implant for both views.

The particular advantage of the above described techniques used in the manufacture of a prosthetic implant to suit a particular form of bone cavity of a patient is that design freedom is given to the surgeon who will be carrying out the implantation, and from his own experience he can select what appears to him to be the optimum profile.

The manufacturer then converts the data which is inputted by the surgeon into visual representations of the implant e.g. two elevational views and a three dimensional view, for return to the surgeon for final approval, before any supply or new manufacture takes place. This places the responsibility for the design shape on the person best qualified to make a suitable judgement for a particular patient, and yet provides a simple system which is easily carried out by the surgeon without any need to have special drawing skills, or special knowledge of drawing office techniques.

Finally, the responsibility for the design is entirely in the hands of the surgeon, and there can be no argument at a later date that the surgeon's design instructions have not been faithfully carried out as he intended.

The use of templates of the above described type comprise one preferred example for use in the invention. However, there are other ways in which a template can be provided which defines the required shape of an implant and which still relies upon input judgement made by the surgeon, but which involves exercise only of simple skills in order to build-up the required outline.

Therefore, in a further preferred example in accordance with the invention, a range of templates may be provided of a general shape appropriate to the implant to be fitted in the bone cavity, and then a selection is made from this range and the selected template is compared with the image outline to see whether it constitutes a suitable match to the profile of the bone cavity, and if necessary an alternative selection is made.

This is then followed by manufacture of an implant of a form corresponding with the selected template, or selection of an implant from a preformed range of implants corresponding with the range of templates and of a form corresponding with the selected template.

According to a second aspect of the invention there is provided a method of manufacture of a prosthetic device of a form to be implanted in a particular bone cavity of a patient and which comprises:

preparing an image of the bone cavity;

providing at least one range of templates of a general shape appropriate to the implant to be fitted in the bone cavity;

making a selection from said range of templates and making a comparison between the selected template and the image to determine whether it constitutes a suitable match to the profile of the bone cavity, and if necessary making an alternative selection(s): and

manufacturing an implant of a form corresponding with the selected template, or making a selection of an implant from a pre-formed range of implant corresponding with the range of templates and of a form corresponding with the selected template.

The comparison may be carried out by placing the image and the selected template one upon the other, with the upper one being transparent so that the underlying one can be viewed.

Therefore, by carrying out a method according to either aspect of the invention, an implant can be supplied which can correspond with the judgement of the surgeon as to the most suitable shape and/or size of template used with the image of the bone cavity, and without any preoperative surgery being required as is the case in the second known technique referred to earlier.

Preferably, a number of different sets of template may be provided, with each set being composed of a range of progressively varying shapes and/or sizes, and the selected templates from each set can then be assembled over the image so as to form a model of the required form of implant.

In the preferred application of the invention to the supply of hip prostheses, the sets of templates may form a two dimensional model built up from a central core, a proximo-medial segment, a proximo-lateral segment and a proximo-anterior segment. The central core may be built up from two portions, comprising a distal shaft to be located over the main tubular portion of the cavity, and a proximal portion to be located in the mouth or proximal end of the cavity.

The template in each set can be supplied in any required variation from one to another e.g. length, diameter, cross-section, and therefore the surgeon, using his skill and judgement and also knowledge of the needs of a particular patient, can then make a selection of the templates which he fits over the image. This information is conveyed to the supplier, who can then readily manufacture a matching

implant, or else supply from stock.

The surgeon then can carry out necessary surgery and pre-formation of the bone cavity, once the implant has been delivered, and then can carry out implantation.

To facilitate accurate pre-preparation of the cavity to receive the selected form of implant, the supplier may also provide a range of forming tools of a form to suit the templates, or be able readily to manufacture forming tools to suit the selected model built up from the templates. This enables a suitable tool profile to be selected, which can adjust the shape of the bone cavity during necessary pre-preparation work, in order to receive the particular form of implant.

A forming tool may be built up from an assembly of rasp components, comprising a core component and one or more additional components slideably mounted on the core and selected to suit the model form. This rasp may be built up in the same way as the femoral rasp can be built up as disclosed in more detail in WO 90/03764.

Conveniently, the image of the bone cavity is formed by X-ray scanning, and in the case of a hip implant, the images will usually be the anterior/posterior (A/P) view and the lateral view. The surgeon will then usually place the two-selected core components over the bone cavity of the A/P view, and then transfer this selection to the lateral view and make any necessary different selection (which may on occasions be a smaller size). The proximo-anterior segment will then be selected from its range and placed over the lateral view, and then the three components will be returned to the A/P view for selection and placement of the medial and proximo-lateral segments.

In the application of the invention to hip implants, preferably the proximal core portion has reference lines which will correspond to the lesser trochanter and the greater trochanter on the patient image.

The invention will now be described in more detail by way of example only, with reference to the accompanying

drawings, in which:

Figure 1 is an X-ray image of an anterior/posterior view of a f moral component of a patient requiring a hip implant, and with one example of a two dimensional model of a required form of implant placed over the image;

Figure 2 is a lateral view of the femoral component with the model transferred thereto;

Figure 3 is a schematic view of a range of templates to form a distal core portion of the model;

Figures 4a and 4b are A/P and lateral views respectively of a proximal core portion of a range which can be used to build up the selected model form;

Figure 5 is a schematic illustration of one of a range of proximal inserts to be used in order to build-up the required model form;

Figure 6 shows schematically three proximal insert components to be used in building-up the required model form;

Figure 7 is a horizontal section illustrating the proximal end of the model built up from three selected components of the three separate insert components shown in figure 6, and fitted around the upper end of the proximal core portion shown in figures 4a and 4b;

Figures 8a and 8b are schematic illustrations of an instruction to the supplier from a surgeon for an implant to be supplied in a form matching that of the selected two dimensional model form built-up by the surgeon and fitting over the X-ray images of the bone cavity;

Figures 9a and 9b are respectively anterior / posterior and lateral views of an image of a femoral bone cavity of a patient into which a prosthetic device is to be implanted;

Figure 10 is a plan view of a further example of template for use with the views of Figures 9a and 9b;

Figure 11 is a plan view of the template of Figure 10 with an applied outline marking of a suggested profile of an implant to be used in the femoral bone cavity of the patient;

Figure 12 shows elevational views of an implant derived

from data extracted from the marked template of Figure 11, and after suitable magnification to correspond with the magnification of the X-ray images;

Figure 13 is a three dimensional illustration of the implant corresponding with Figure 12 and obtained from computer generated graphics derived from the data extracted from Figure 12;

Figure 14 shows a first stage of converting a two dimensional image to three dimensional form;

Figure 15 shows a further stage;

Figure 16 is a section taken on A-A in Figure 15; and,

Figure 17 is a flow diagram showing the successive stages involved in the supply of a prosthetic implant of a design derived from data supplied by the surgeon involved in the implantation.

Referring first to Figures 1 to 8 of the drawings, there will be disclosed in detail one example of a method of manufacturing a prosthetic implant of a form to suit the particular requirements of a patient. This example will be described in connection with the manufacture of a replacement hip joint for a human patient, but it should be understood that this is by way of example only, and that the features of the invention may be applied generally in the manufacture and supply of prosthetic implants of other types, such as knee implants and for human or animal use.

Figures 1 and 2 are A / P and lateral views of X-ray images of a proximal femur 10 having a natural bone cavity 11, which is intended to receive a prosthetic implant. The two X-ray images prepared of the bone cavity appear on a transparent film, which can be placed on a suitable support surface, so that templates can be placed thereon in order to build up a two dimensional model of a required implant form.

Figures 1 and 2 are A/P and lateral views of a left femur, and show how a set of templates can be laid thereon to build up the required model form.

In the illustrated arrangement, five different template components are provided, and comprising first and second core

portions 12 and 13, with the portion 12 comprising the model form of the distal portion of the implant, and which usually is in the form of a circular cross-section rod. The portion 13 forms a model of the proximal or head portion of the implant.

The portion 12 will be supplied in a range of sizes e.g. in varying length and/or diameter, as shown in figure 3, and the portion 13 also will be provided in a range of sizes and of varying cross section, and which is shown in figures 4a and 4b. The lateral extension of the simulated head 14 from the portion 13 also may be varied within a range of sizes. Also, reference lines 15 and 16 may be provided to enable the portion 13 to be lined up with the lesser trochanter and the greater trochanter respectively on the X-ray images of the bone cavity profile.

The further components of the sets of template comprise medial component 17 and lateral component 18 shown in figure 1, and anterior component 19 shown in figure 2.

Usually, the surgeon will place suitably selected core portions 12 and 13 initially over the A/P view, and then transfer this selection to the lateral view and if necessary make an alternative selection, (if required usually a smaller size). The surgeon would then apply a selected anterior component 19 to fit over the lateral view, and then return these three components to the A/P view for application of selected medial component 17 and lateral component 18. The surgeon will use his skill and judgement as well as his knowledge of the needs of the patient, in determining the appropriate profile of each model segment from the ranges which will be made available to him. Once the surgeon is satisfied with his selection he will then complete an instruction to the manufacturer/supplier, in the form of a pro-forma order instruction as shown in figures 8a and 8b, giving his selection of the five components of the model, with suitable identifying characters. Upon receipt, a matching form of implant can be supplied from stock or else manufactured from data derived previously from the model

segments.

Accordingly in its most general sense the invention provides a method of manufacture of a prosthetic implant of a form to fit a particular bone cavity of a patient and which comprises preparing an image of the bone cavity, providing at least one range of templates of a general shape appropriate to the implant to be fitted in the bone cavity, making a selection from this range of template and placing the selected template on the image to determine whether it constitutes a suitable match to the profile of the bone cavity, and if necessary making an alternative selection(s), and manufacturing an implant of a form corresponding with the selected template, or making a selection of an implant from a pre-formed range of implants corresponding with the range of templates and of a form corresponding with the selected template.

However, in the illustrated embodiment, five sets of templates are provided, with each set having a suitable range of components, and the image provided is a pair of X-ray images in the A/P view and the lateral view.

In addition, to facilitate accurate pre-preparation of the cavity to receive the selected implant form, the supplier may provide a range of forming tools of a form to suit the built-up model, or has stored data corresponding to the selected model to enable a forming tool to be built up to match this model, whereby a suitable tool profile can be selected which can adjust the shape of the bone cavity where necessary in order to receive the implant.

The forming tool may be built-up from an assembly of rasp components, comprising a core component, and one or more additional component slideably mounted thereon, in a manner disclosed in more detail in WO 90/03764. Alternatively, the tool may be constructed as a one-off construction.

Conveniently, the images of the bone cavity are formed by X-ray scanning, but the invention is not restricted to such means for providing the images.

Thus, in the practical application of the invention, an

analysis of data will be obtained from CT scans and intra-operative moulds of femoral cavities, so that acceptable shape and size characteristics of prepared cavities and implants can be determined. These cavities are then divided into parts comprising the central core (corresponding to portions 12 and 13), a proximo-medial segment (17) a proximo-lateral segment (18) and a proximo-anterior segment (19). A range of different shapes and sizes of the segments will be determined.

Radiographic templates of all the templates of the segments, with appropriate magnification, will be provided to the surgeon who can assemble them in an "Identikit Fashion" to produce anterio-posterio and medio-lateral profiles considered best suited to the individual case. A forming tool in a form of a broach can be assembled from individual pre-manufactures modules which are slideably mounted thereon. The composite geometry is suitably processed and fed to a CNC machine to manufacture a matching implant from a range of suitable blanks and precuts. The assembled broach and matching implant are supplied to the surgeon who uses them in a traditional manner to carry out total hip replacement. If it should be decided that cement should be used in the implantation, a smaller size implant would be manufactured, to allow for subsequent application of a uniform cement mantle.

The disclosed embodiment of the invention enables the supply of an assembled modular broach for surgical preparation of the femoral cavity to surgeon specified design determined by X-ray or CT scan templating, combined with pre-operative manufacture of a matching hip prosthesis.

Referring now to Figures 9a and 9b to Figures 13, there will be described a further preferred example of method of manufacture of a prosthetic device in accordance with the invention, in which an alternative type of template is used.

Figures 9a and 9b show anterior / posterior and lateral views of an x-ray image of a femoral bone cavity, and Figure 10 shows a template which can have the required outline shape

of an implant marked thereon which is appropriate to the bone cavity, whereby to provide a template which defines the required shape of the implant which can be compared with the x-ray image views of the bone cavity, usually by superposing the template over the views shown in Figures 9a and 9b.

The reference lines a and b in Figure 10 correspond with the centre lines of the x-ray views 9a and 9b respectively, and once the reference lines shown in Figure 10 are lined-up with appropriate references on the x-ray images, the surgeon who will be carrying out the implant surgery can then apply a suggested outline profile for the implant as shown in Figure 11, again with references a and b corresponding with views 9a and 9b. This outline can be marked easily by the surgeon by making small crosses on the respective reference lines, and this is then compared with the respective x-ray images. The surgeon will use his expertise and experience, in his interpretation of the required outline in relation to the particular X-ray image of the bone cavity, to arrive at an optimum outline.

After the surgeon is satisfied with the visual comparison which he makes, or if necessary after providing an alternative implant shape for comparison with the image, then this information is passed back to the supplier / manufacturer of implants. The information on the template is then extracted and converted into digital form, from which is derived outline elevational views of the particular design of implant, as shown in Figure 12, in which references a and b designate the elevational views of the implant to suit the anterior / posterior and lateral views of Figures 9a and 9b respectively.

The views created for Figures 12a and 12b are derived from Figure 9a and 9b, and to a magnification which corresponds with the magnification factor of the originally formed X-ray images. The magnification factor will be presented on the X-ray images, and also on Figures 10 and 11. The views of Figures 12a and 12b will be on transparent sheet which can then be compared with the X-ray images.

In addition, a computer generated graphics system is operated, with data derived from the template, to form a three dimensional representation of the required implant as shown in Figure 13.

The views of Figures 12 and 13 and X-ray templates are then conveyed to the surgeon for final approval, before the required implant is taken from stock, or manufactured to order.

Figures 14 to 16 shows successive stages in the conversion of a two dimensional image to a suitable three dimensional implant form. To achieve this, the following preferred objectives should be borne in mind:

1. generate smooth points to give a shape that can be produced in the bone cavity;

2. determine the optimal distal diameter for circular cross-sections;

3. project the radius of the distal cross-section along the medial, lateral, anterior and posterior profiles;

4. tangentially join these with straight lines; or curved arcs could be used as an alternative.

Figure 17 shows a flow diagram of successive stages which will be involved in the supply of custom designed implants to suit the requirements of the surgeon.

CLAIMS

1. A method of manufacture of a prosthetic device of a form to be implanted in a particular bone cavity of a patient and which comprises:

preparing an image of the bone cavity:

providing a template which defines the required shape of an implant which is appropriate to the particular bone cavity:

visually comparing the image and the implant shape defined by the template to determine whether the implant shape constitutes a suitable match to the profile of the bone cavity, and if necessary providing an alternative implant shape for comparison with the image: and.

manufacturing an implant of a form corresponding with the implant shape defined by the template after an approved implant shape has been determined.

2. A method according to Claim 1, in which the visual comparison takes place by arranging the image and the template one over the other.

3. A method according to Claim 2, in which the template is transparent, and is positioned over the image.

4. A method according to any one of Claims 1 to 3, in which the template has the required shape of an implant applied thereon by supplying a template sheet having reference lines thereon which are lined-up with corresponding references on the image, and then marking out by manual means the selection of an appropriate outline for the implant on the template.

5. A method according to Claim 4, in which the template with the marked outline has the data thereon converted into digital form, and from which is derived outline elevational views of the required implant, and also a three dimensional illustration for review and approval prior to supply of the required design of implant.

6. A method according to any one of Claims 1 to 5, in

which the images of the bone cavity comprise anterior / posterior and lateral views of a femoral bone cavity. and the template has reference lines corresponding with each view, so that marked outlines can be applied to the template of the required outline of the implant for both views.

7. A method according to Claim 1, in which a range of templates is provided of a general shape appropriate to the implant to be fitted in the bone cavity. and a selection is made from this range and the selected template is compared with the image outline to see whether it constitutes a suitable match to the profile of the bone cavity. and if necessary an alternative selection is made. which is then followed by manufacture of an implant of a form corresponding with the selected template. or selection of an implant from a pre-formed range of implant corresponding with the range of templates and of a form corresponding with the selected templates.

8. A method of manufacture of a prosthetic device of a form to be implanted in a particular bone cavity of a patient and which comprises:

preparing an image of the bone cavity;

providing at least one range of templates of a general shape appropriate to the implant to be fitted in the bone cavity;

making a selection from said range of templates and making a comparison between the selected template and the image to determine whether it constitutes a suitable match to the profile of the bone cavity. and if necessary making an alternative selection(s); and,

manufacturing an implant of a form corresponding with the selected template. or making a selection of an implant from a preformed range of implant corresponding with the range of templates and of a form corresponding with the selected template.

9. A method according to Claim 8. in which the

comparison is carried out by placing the image and the selected template one upon the other, with the upper one being transparent so that the underlying one can be viewed.

10. A method according to Claim 8 or 9, in which a number of different sets of template are provided, with each set being composed of a range of progressively varying shapes and / or sizes, and the selected templates from each set then being assembled over the image so as to form a model of the required form of implant.

11. A method according to Claim 10 and carried out to manufacture a hip joint prosthesis, in which the sets of templates form a two dimensional model built-up from a central core, a proximo-medial segment, a proximo-lateral segment and a proximo-anterior segment.

12. A method according to Claim 11, in which the central core is built-up from two portions, comprising a distal shaft to be located over the main tubular portion of the cavity, and a proximal portion to be located in the mouth or proximal end of the cavity.

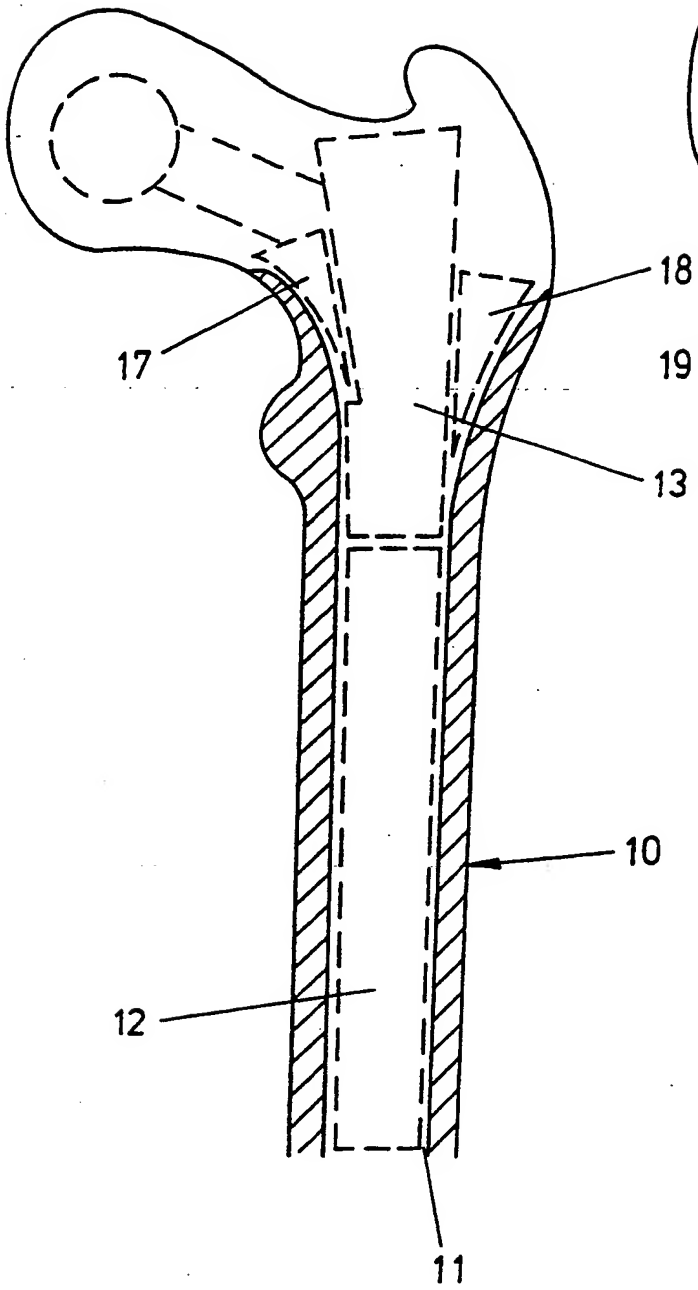


FIG. 1

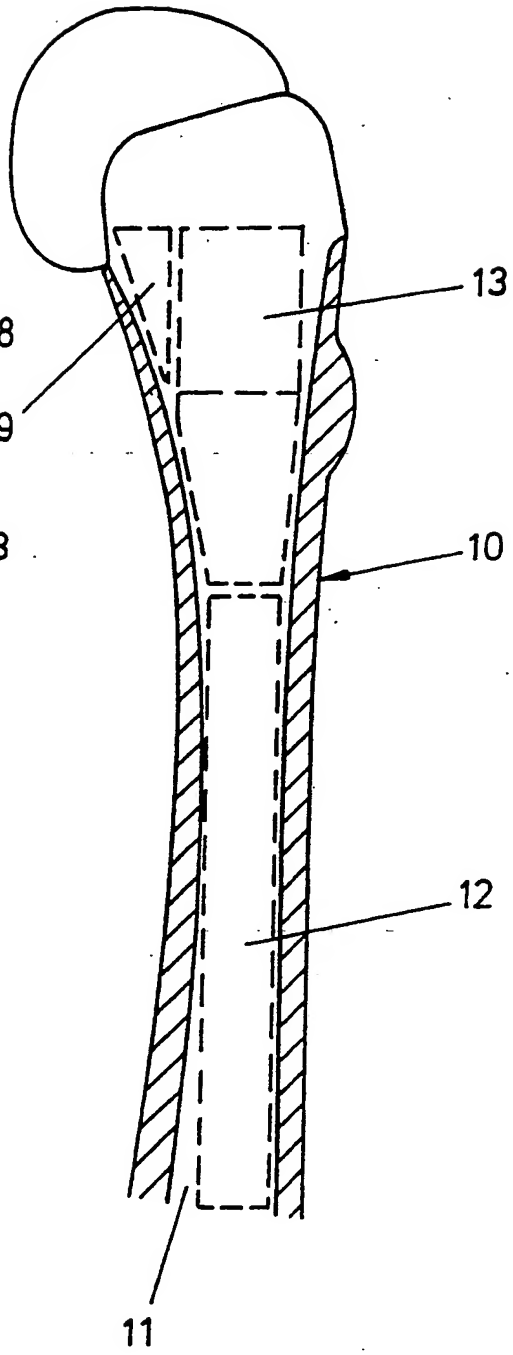


FIG. 2

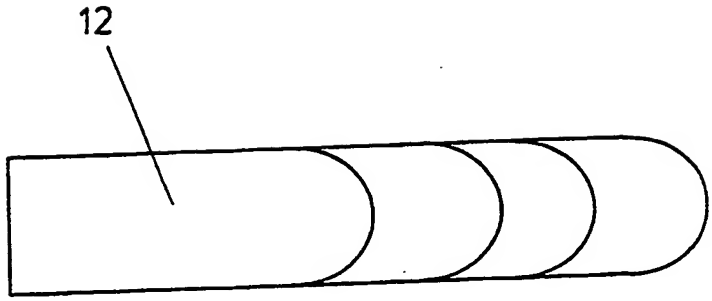


FIG. 3

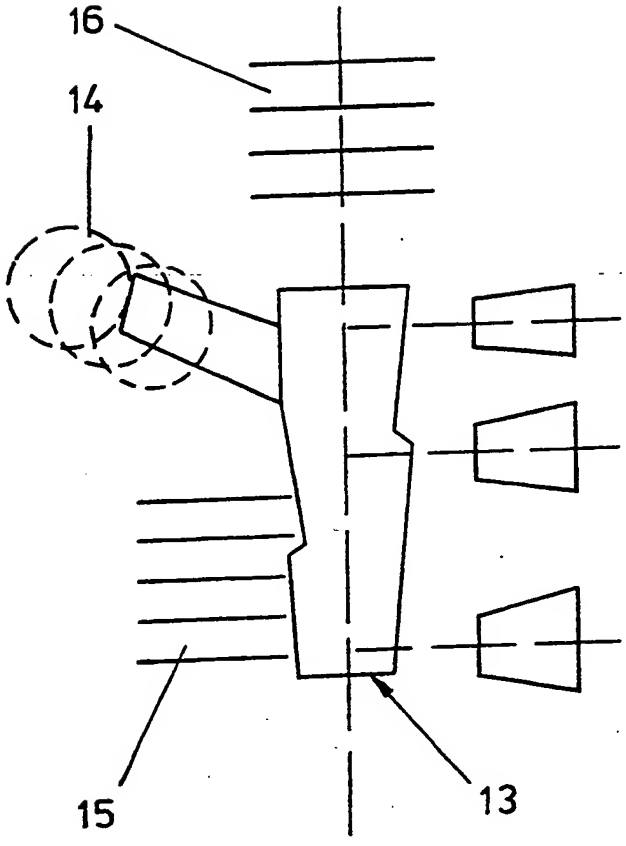


FIG. 4a

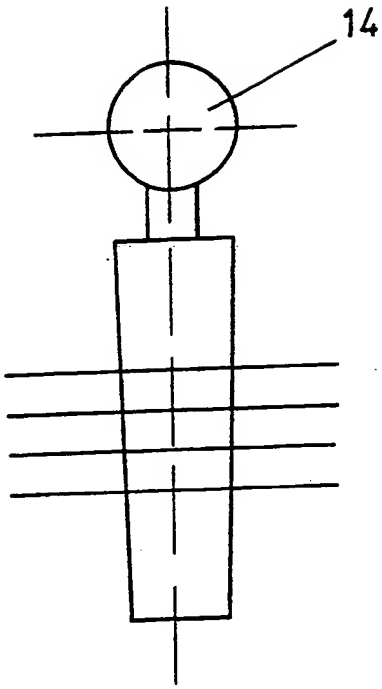


FIG. 4b

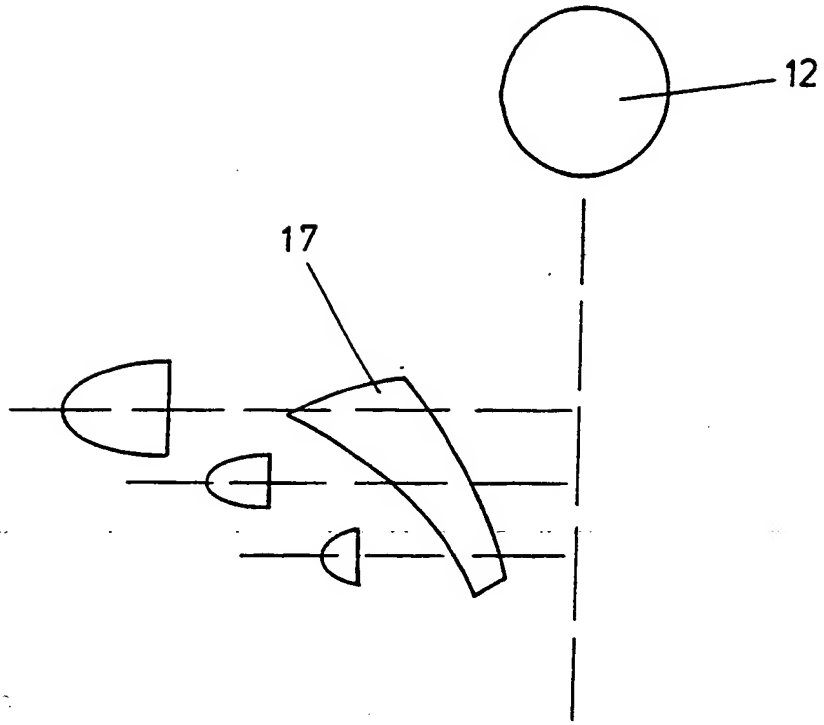
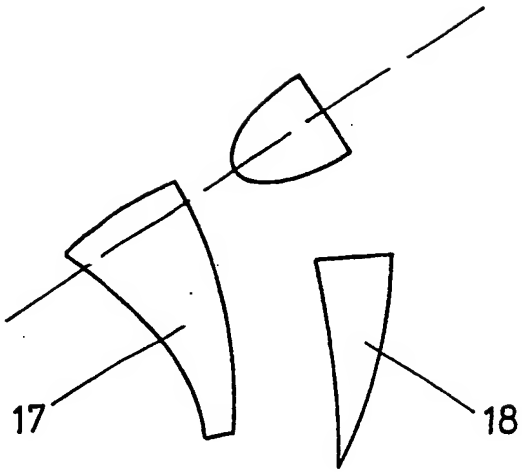
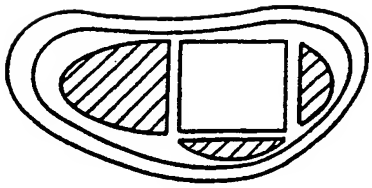


FIG. 5





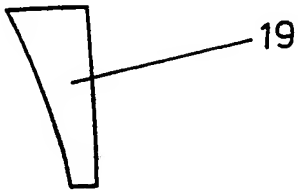


FIG. 7

FIG. 6

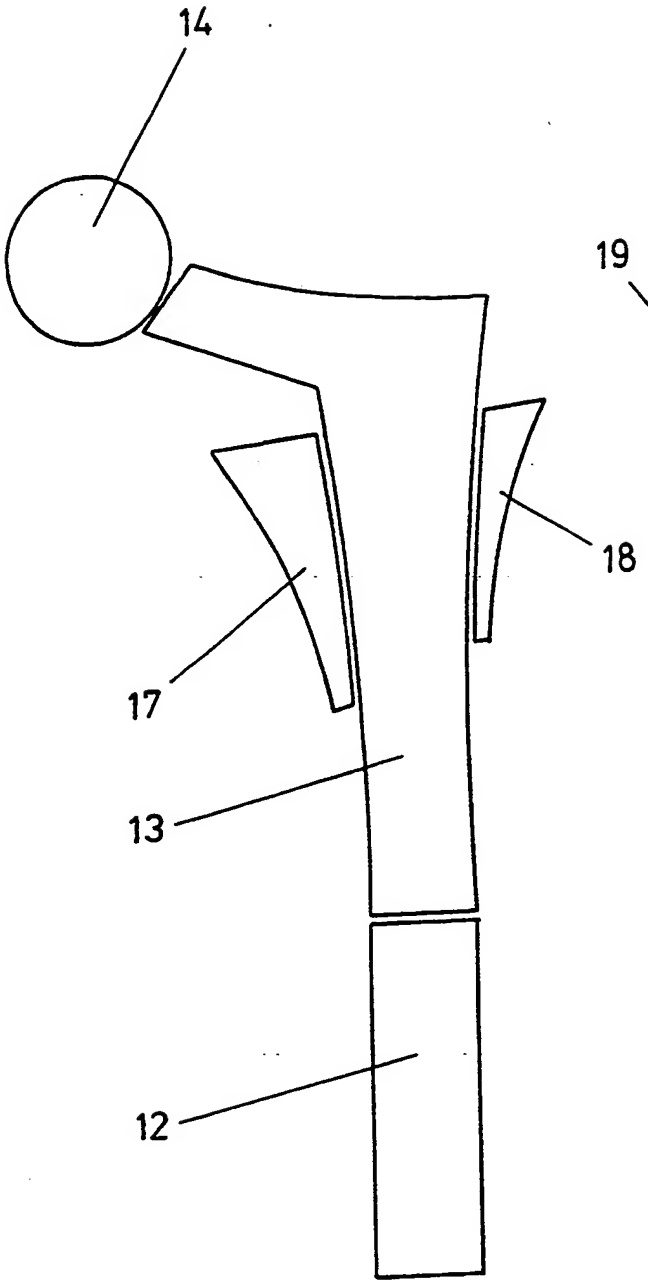


FIG. 8a

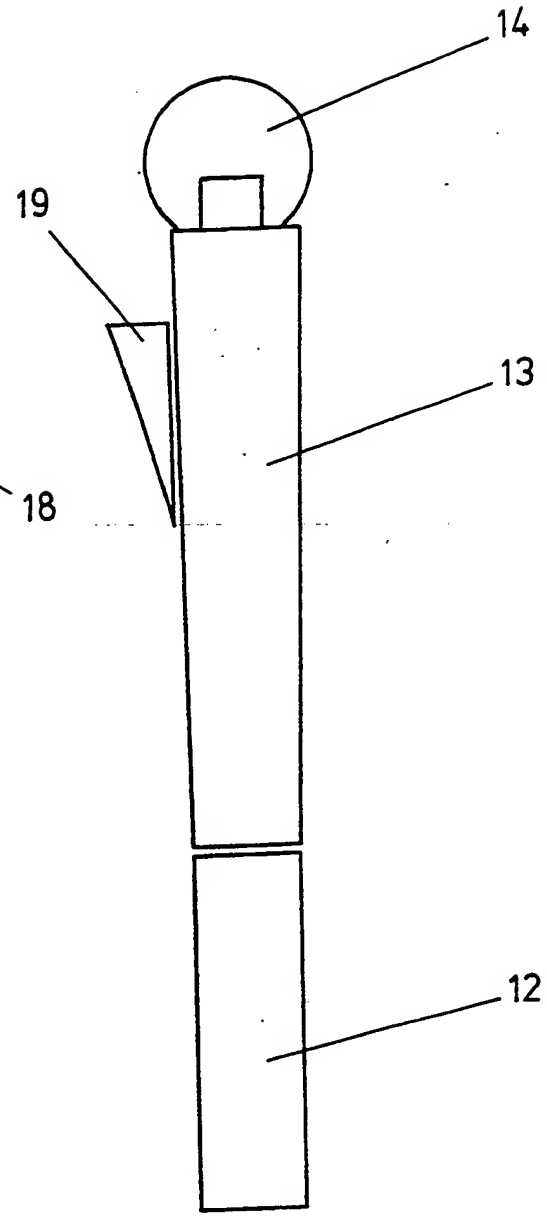


FIG. 8b

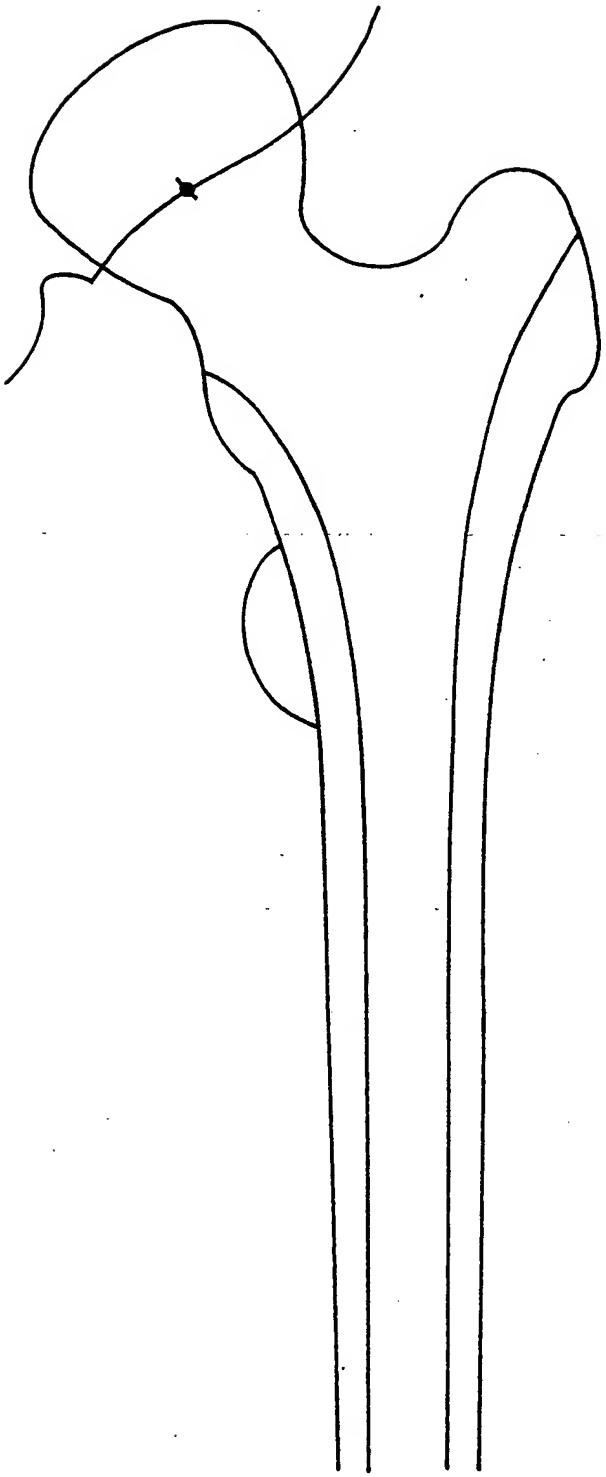


FIG. 9a

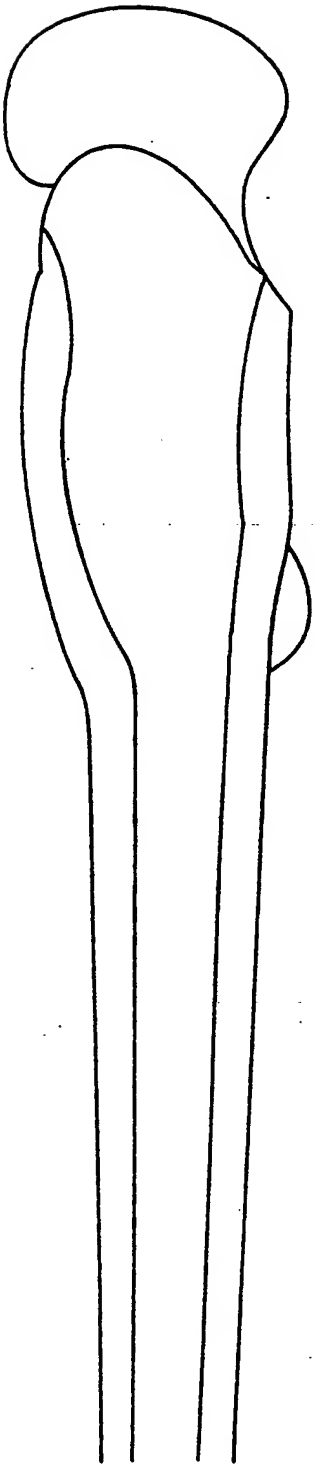
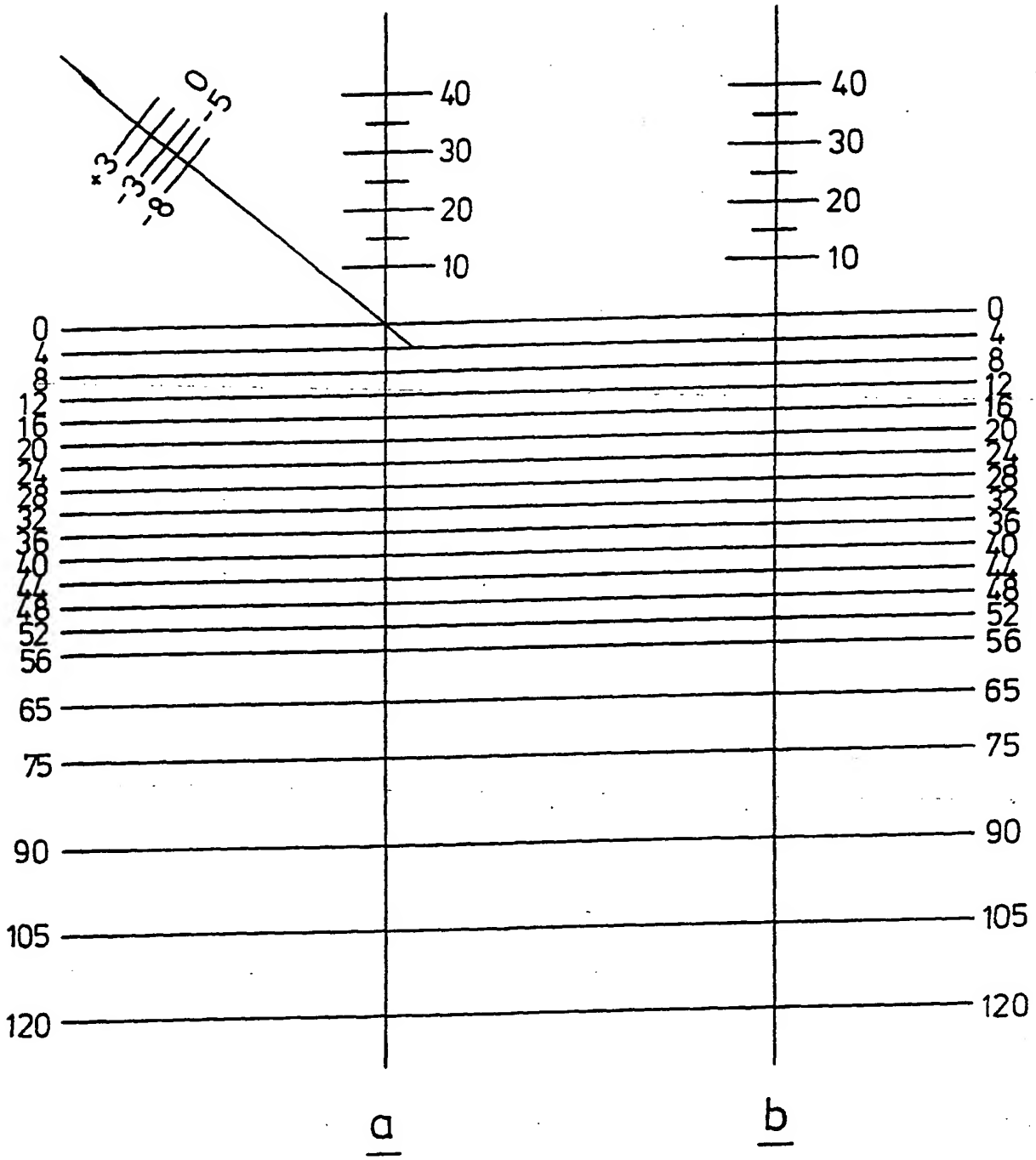


FIG. 9b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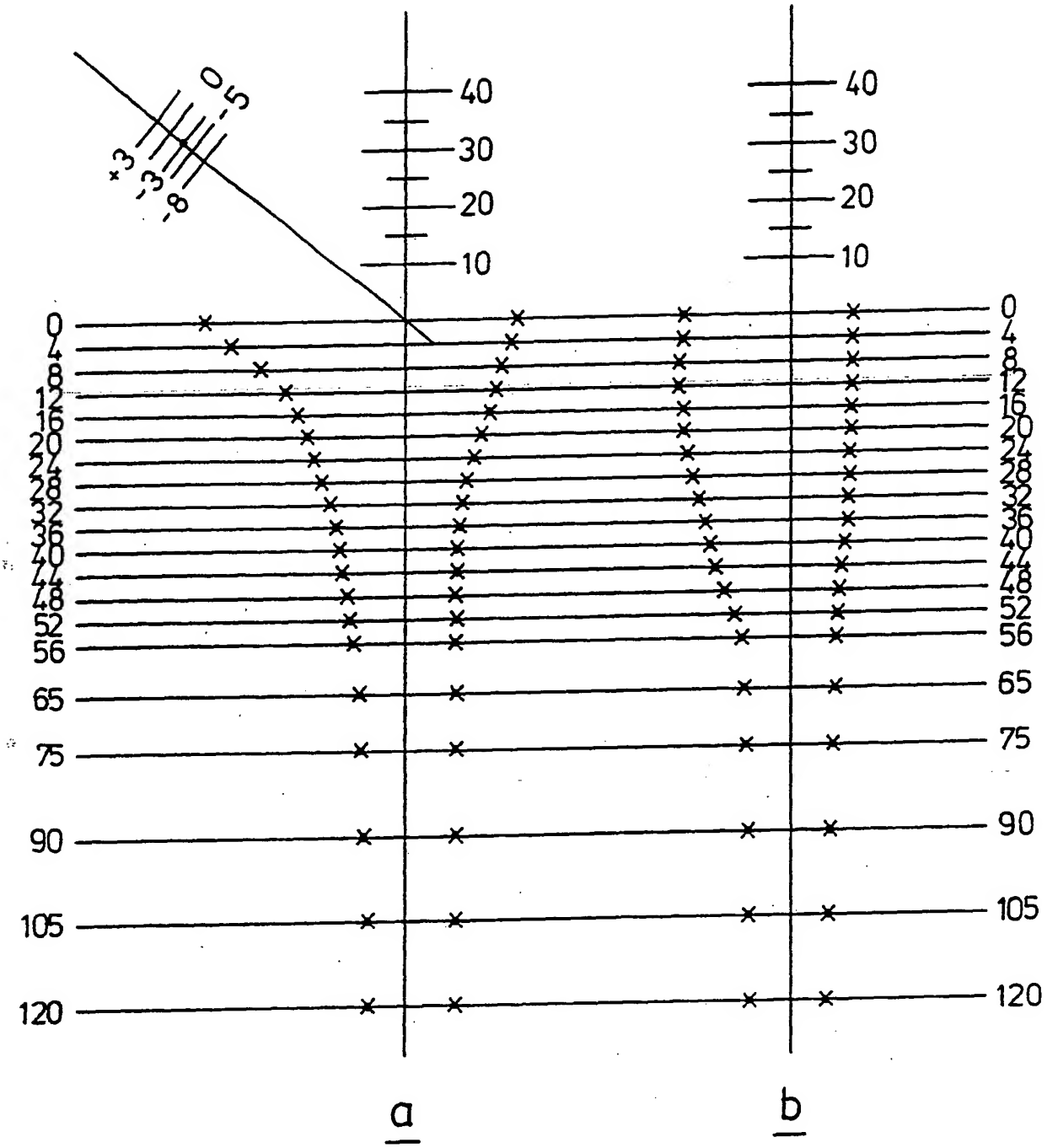
75
90
105
120
a
b

FIG. 10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105
120
a
b

FIG. 11

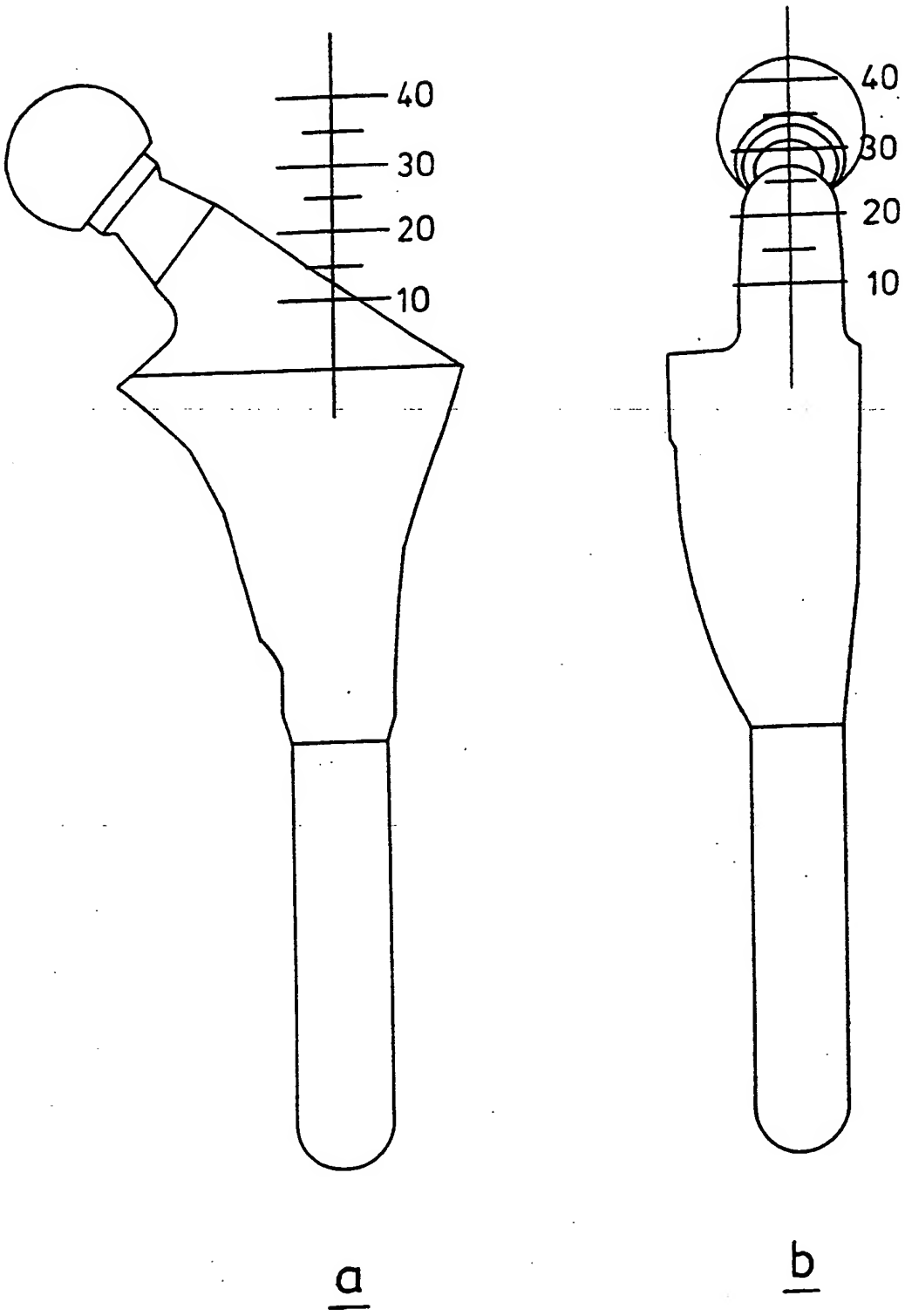

FIG. 12

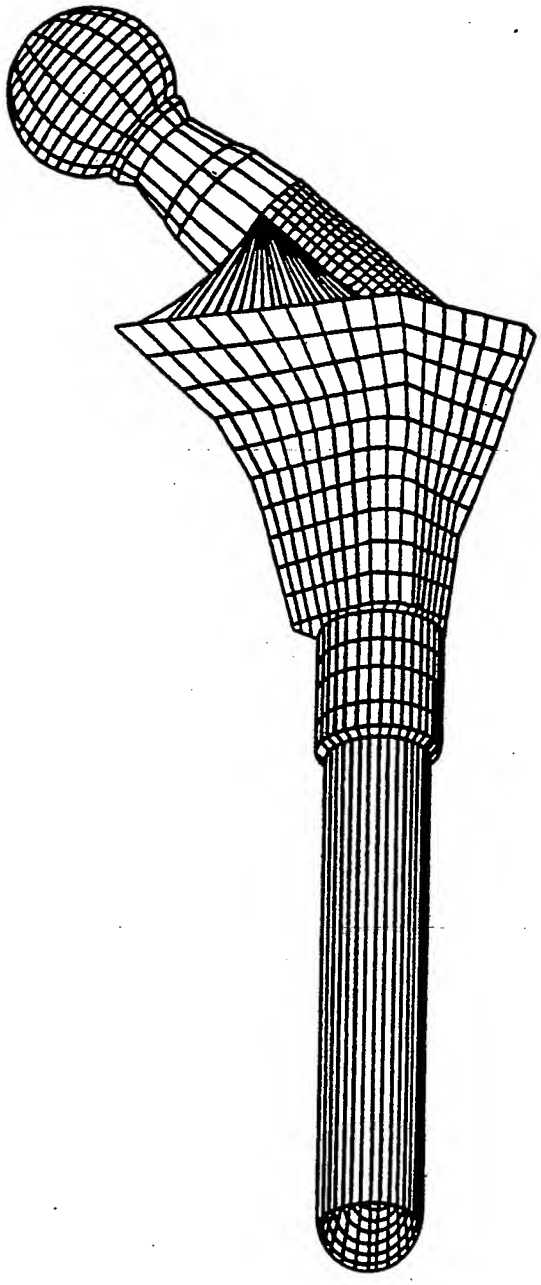

FIG. -13

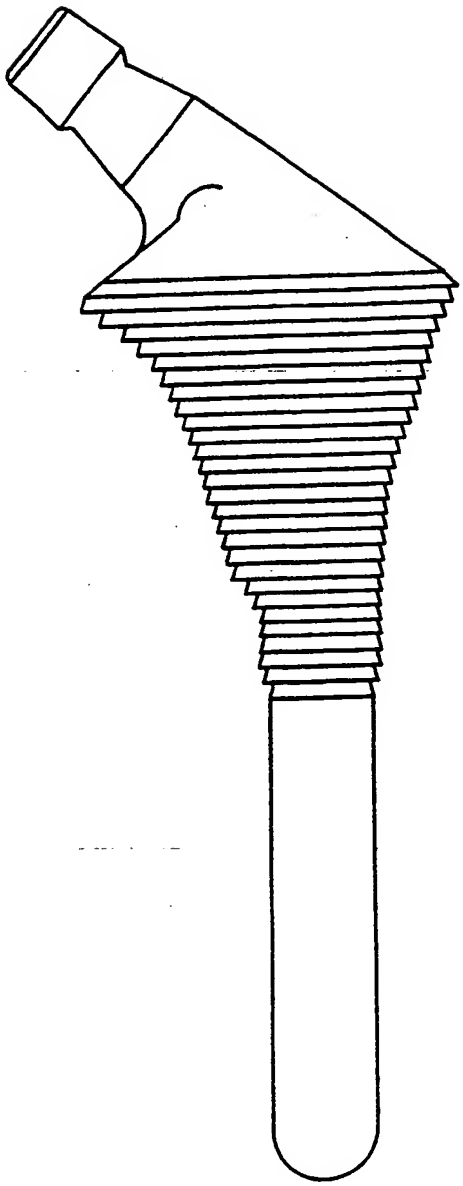

FIG. 14

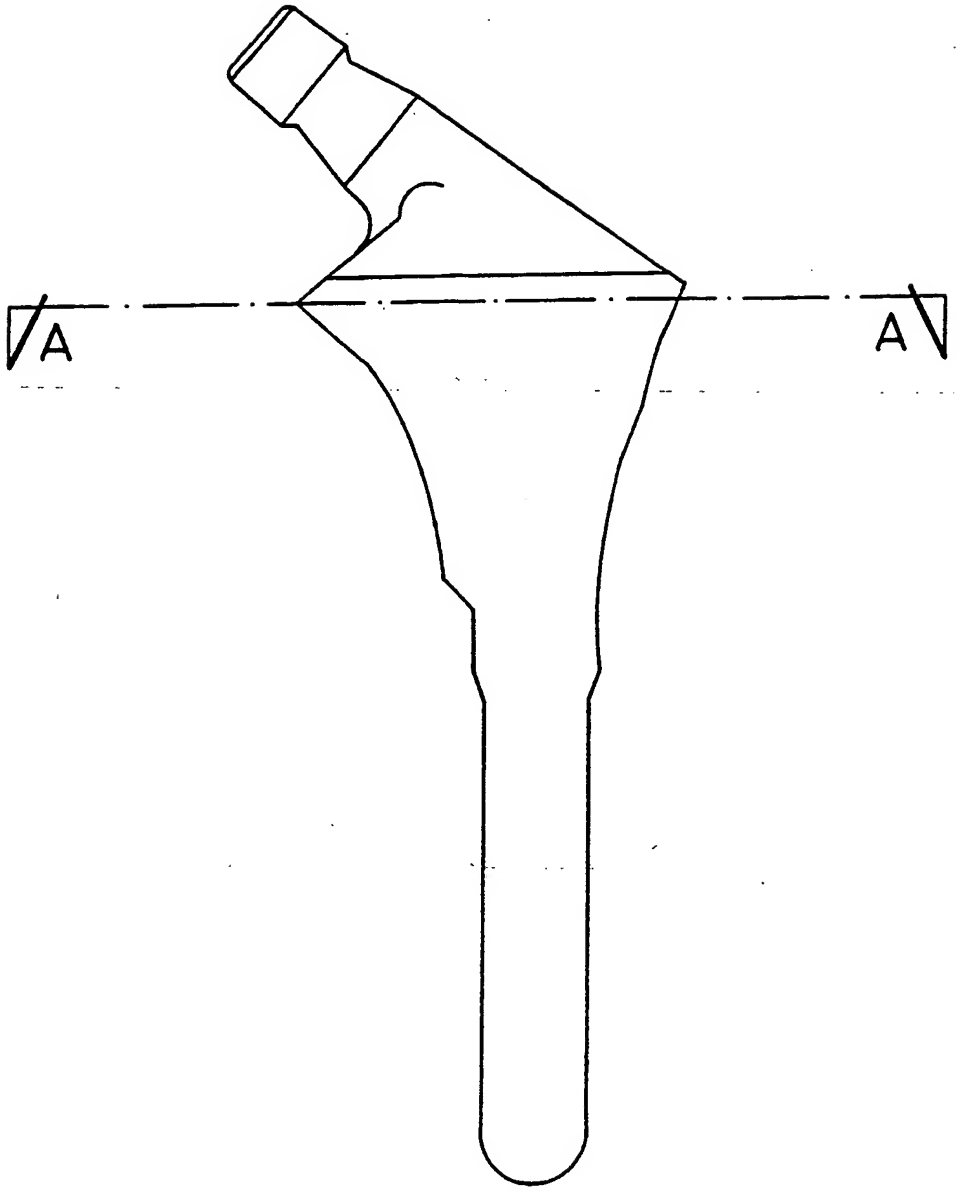

FIG. 15

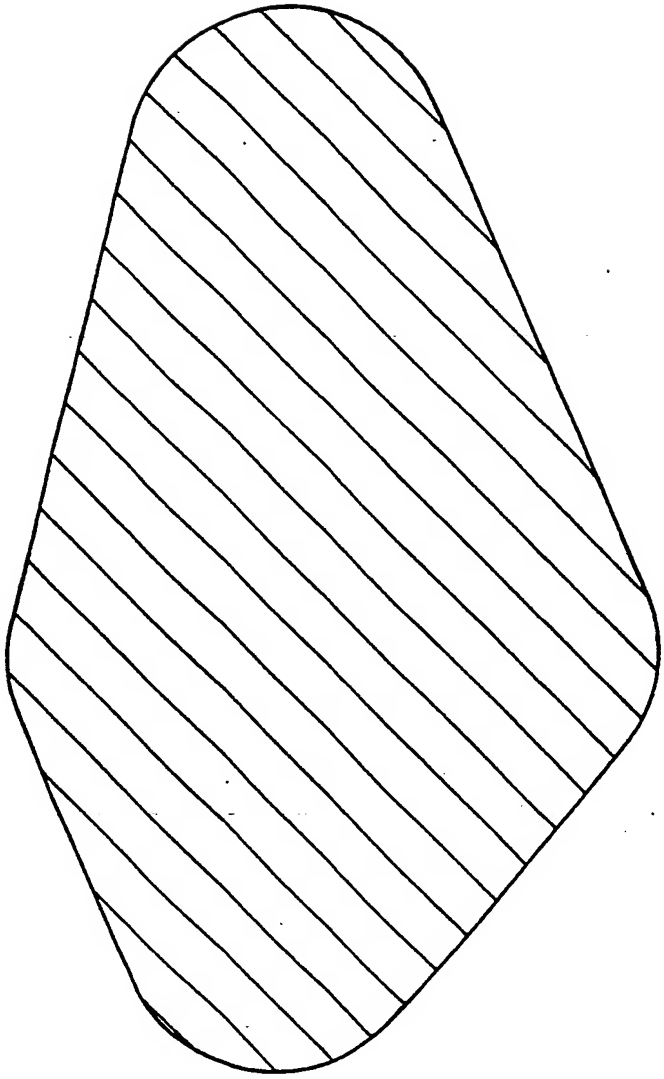

FIG. 16

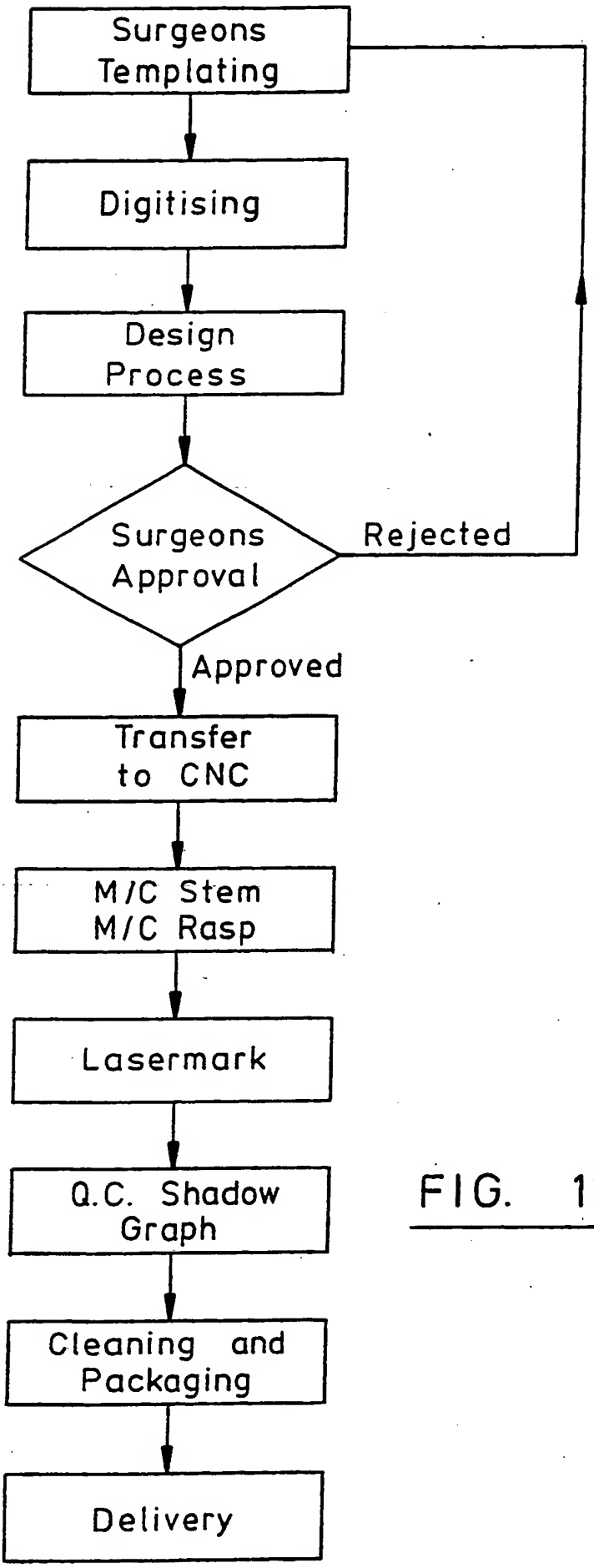
Surgeons Templating
Digitising
Design Process
Surgeons Approval
Rejected
Approved
Transfer to CNC
M/C Stem M/C Rasp
Lasermark
Q.C. Shadow Graph
Cleaning and Packaging
Delivery

FIG. 17

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl.5 . A 61 F 2/30.

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl.5	A 61 F A 61 B

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No.[13]
X	EP,A,0163121 (WALDEMAR LINK) 4 December 1985, see the abstract; page 8, line 5 - page 9, line 26; figures	1-4,6,7 ,8-10
Y		11,12
X	LE NOUVEL AUTOMATISME, vol. 30, no. 55, June 1985, (Paris, FR), J.-C. MORETTON et al.: "Problèmes de prothèse, problèmes de C.F.A.O.", pages 50-54, see page 52, column 1, line 1 - column 2, line 8; figure 2; page 53, figure	1-6
X	FR,A,2577697 (B.J.-C. CHALMOND) 22 August 1986, see page 4, lines 1-19; page 4, line 34 - page 5, line 4; page 8, lines 10-17	1-5
Y	EP,A,0149527 (UNIVERSITY OF EXETER) 24 July 1985, see page 4, lines 8-18; figures 1-3	11,12

-/-

° Special categories of cited documents : [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
17-09-1991	08 OCT 1991
International Searching Authority	Signature of Authorized Officer
EUROPEAN PATENT OFFICE	MISS I. TAZELAAR

Form PCT/ISA/210 (second sheet) (January 1985)

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category °	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	EP,A,0273871 (G. CREMASCOLI) 6 July 1988, see the abstract; figures 7-11 ---	11
A	EP,A,0366945 (W. HERRMANN AG) 9 May 1990, see figures ---	11
A	BIOMEDIZINISCHE TECHNIK, vol. 33, no. 6, June 1988, (Berlin, DE), "Mit dem Computer zum massgeschneiderten Hüftgelenk", pages 153,154, see page 154, column 1, line 22 - column 2, line 28 -----	1

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. GB 9100936 SA 48419

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 26/09/91
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
EP-A- 0163121	04-12-85	DE-A-	3417609	14-11-85
		DE-A-	3564188	15-09-88
		US-A-	4658808	21-04-87
FR-A- 2577697	22-08-86	None		
EP-A- 0149527	24-07-85	DE-A-	3566610	12-01-89
		GB-A,B	2153233	21-08-85
		US-A-	4753657	28-06-88
EP-A- 0273871	06-07-88	None		
EP-A- 0366945	09-05-90	CH-A-	675962	30-11-90